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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the PATENT application of

Durward I. Faries, Jr. et al.

Serial No.: 10/016,128 Group Art Unit: 3767

Filed: December 17, 2001 Examiner: Witczak, Catherine

Technology Center: 3700 Confirmation No.: 4172

For: METHOD AND APPARATUS FOR HEATING SOLUTIONS WITHIN INTRAVENOUS LINES TO DESIRED TEMPERATURES DURING INFUSION

APPEAL BRIEF

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is presented pursuant to the Notice of Appeal filed on April 17, 2008. The brief is filed pursuant to the requirements of 37 C.F.R. §41.37.

(1) Real Party in Interest

The current patent owner or real party in interest is Medical Solutions, Inc., the assignee of record, which is a corporation duly organized and existing under the laws of the state of Virginia and having a place of business at 3901 Centerview Drive, Suite L, Chantilly, Virginia 20151.

(2) Related Appeals and Interferences

Appellant had previously filed a Notice of Appeal (on or about March 21, 2007) and a corresponding Appeal Brief (on or about July 13, 2007) for the subject application. In response to the Appeal Brief, the Examiner issued the outstanding Office Action of October 18, 2007. Appellant is currently unaware of any other prior or pending appeals, judicial proceedings or interferences which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

Claims 1 - 16 and 24 - 50 have been canceled.

Claims 17, 51 and 57 are currently rejected under 35 U.S.C. §112, first paragraph, and are on appeal.

Claims 17 - 23 and 51 - 62 are currently rejected under 35 U.S.C. §103(a) and are on appeal.

(4) Status of Amendments

No amendments After-Final rejection have been submitted since this Appeal was initiated in response to a Non-Final Office Action received after the filing of an Appeal Brief.

(5) Summary of Claimed Subject Matter

Independent claim 17 is directed toward a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device (e.g., See Fig. 2; Specification Page 5, lines 26 - 29; Page 8, lines 8 - 9; and Page 21, lines 14 - 15). The cassette comprises: fluid line tubing including an inlet tubing portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet tubing portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet terminals each including a connector for connection to portions of the intravenous fluid line (e.g., See Fig. 2; Specification Page 8, lines 9 - 10; Page 9, lines 5 - 6; and Page 10, lines 1 - 6); wherein the fluid line tubing further includes a spiral portion including a plurality of nested tubing sections in fluid communication with the inlet and outlet tubing portions and arranged adjacent each other to directly transfer heat between the adjacent tubing sections to heat the fluid from the intravenous fluid line, each tubing section defining a path for the fluid from the intravenous fluid line to flow in a particular direction, and wherein the fluid flow direction within each tubing section is opposite the fluid flow direction within each tubing section adjacent that section (e.g., See Fig. 2; Specification Page 8, lines 11 - 20); wherein the quantity of tubing sections within the spiral portion is based on providing a residence time for the fluid within the fluid line tubing enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F (e.g., See Fig. 2; Specification Page 8, lines 20 - 21; Page 16, lines 9 - 11; and Page 21, lines 14 - 15).

Independent claim 51 is directed toward a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device (e.g., See Fig. 2; Specification Page 5, lines 26 - 29; Page 8, lines 8 - 9; and Page 21, lines 14 - 15). The cassette comprises: fluid flow means (e.g., cassette body 57; See Fig. 2; Specification Page 8, lines 8 - 12; and Page 18, line 31 to Page 19, line 4) including an inlet portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet portions each including a connector for connection to portions of the intravenous fluid line (e.g., See Fig. 2; Specification Page 8, lines 9 - 10; Page 9, lines 5 - 6; and Page 10, lines 1 - 6); wherein the fluid flow means further includes a plurality of concentric sections in fluid communication with the inlet and outlet portions and arranged adjacent each other to directly transfer heat between the adjacent sections to heat the fluid from the intravenous fluid line, each concentric section defining a path for the fluid from the intravenous fluid line to flow in a particular direction, and wherein the fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section (e.g., See Fig. 2; Specification Page 8, lines 11 - 20); wherein the quantity of sections is based on providing a residence time for the fluid within the fluid flow means enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F (e.g., See Fig. 2; Specification Page 8, lines 20 - 21; Page 16, lines 9 - 11; and Page 21, lines 14 - 15).

Independent claim 57 is directed toward a fluid cassette to receive fluid from an intravenous

fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device (e.g., See Fig. 2; Specification Page 5, lines 26 - 29; Page 8, lines 8 - 9; and Page 21, lines 14 - 15). The cassette comprises: a fluid conduit including an inlet portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet portions each including a connector for connection to portions of the intravenous fluid line (e.g., See Fig. 2; Specification Page 8, lines 9 - 10; Page 9, lines 5 - 6; and Page 10, lines 1 - 6); wherein the fluid conduit further includes a plurality of concentric sections in fluid communication with the inlet and outlet portions and arranged adjacent each other to directly transfer heat between the adjacent sections to heat the fluid from the intravenous fluid line, each concentric section defining a path for the fluid from the intravenous fluid line to flow in a particular direction, and wherein the fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section (e.g., See Fig. 2; Specification Page 8, lines 11 - 20); wherein the quantity of sections is based on providing a residence time for the fluid within the fluid conduit enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F (e.g., See Fig. 2; Specification Page 8, lines 20 - 21; Page 16, lines 9 - 11; and Page 21, lines 14 - 15).

(6) Grounds of Rejection to be Reviewed on Appeal

(A) Whether claims 17, 51 and 57 are unpatentable under 35 U.S.C.§112, first paragraph, as being based on a disclosure failing to comply with the written description requirement.

(B) Whether claims 17 - 23 and 51 - 62 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. 2001/0009610 (Augustine et al.) as modified by U.S. Patent No. 6,788,885 (Mitsunaga et al.) in further view of U.S. Patent No. 4,747,450 (Ikegame et al.).

(7) Argument

(A) Rejection of claims 17, 51 and 57 under the written description requirement of 35 U.S.C. §112, first paragraph

In the Office Action of October 18, 2007, the Examiner rejected claims 17, 51 and 57 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

(A.1) Legal Analysis

35 U.S.C. §112, first paragraph, states:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms so as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

In order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude the inventor had possession of the claimed invention. M.P.E.P. §2163 (citing Moba, B.V. v. Diamond Automation, Inc. 66 USPQ.2d 1429, 1438 (Fed. Cir. 2003)). It is well accepted that a satisfactory description may be in the claims or any portion of the originally filed specification. M.P.E.P. §2163. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using descriptive means (e.g., words, structures, figures, diagrams and formulas) that fully set forth the claimed invention. M.P.E.P. §2163 (citing Lockwood v. American Airlines, Inc., 41 USPQ.2d 1961, 1966 (Fed. Cir. 1997)).

(A.2) Claims 17, 51 and 57 are patentable in view of the Written Description Requirement of 35 U.S.C. §112, first paragraph

Initially, independent claims 17, 51 and 57 each recite the features of the quantity of sections being based on providing a residence time for the fluid within the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F.

The Examiner takes the position that the claimed features of enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F are not described in the specification in such a way as to reasonably convey to one skilled in the relevant arts that the inventors, at the time the application was filed, had possession of the claimed invention.

However, these features are expressly recited in the specification. In particular, the specification discloses that the cassette may include any quantity of sections to produce a residence time within the warming device sufficient to heat the fluid, and that the configuration of the cassette provides a long residence time for fluid flowing therein, thereby ensuring that fluid exiting the cassette attains the desired temperature (e.g., See Specification Page 8, lines 20 - 21; and Page 16, lines 9 - 11). Thus, the specification clearly indicates that the quantity of sections provides a residence time for the fluid within the warming device to enable the warming device to heat the fluid to attain the desired temperature as recited in the claims.

In addition, the specification discloses that the (desired) fluid temperature may be predetermined or entered by a user, where the warming device heats fluid to temperatures in the approximate range of 60° F - 160° F (e.g., See Specification Page 21, lines 14 - 15). Thus, the specification clearly indicates that the warming device heats the fluid to desired temperatures in the

range of 60° F - 160° F as recited in the claims. Accordingly, the specification clearly supports the features of the quantity of sections being based on providing a residence time for the fluid within the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F as recited in the claims, and this rejection is considered improper.

(B) Rejection under 35 U.S.C. §103(a) Over the Combination of the Augustine et al. Publication, and Mitsunaga et al. and Ikegame et al. Patents

In the Office Action of October 18, 2007, the Examiner rejected claims 17 - 23 and 51 - 62 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0009610 (Augustine et al.) as modified by U.S. Patent No. 6,788,885 (Mitsunaga et al.) in further view of U.S. Patent No. 4,747,450 (Ikegame et al.).

(B.1) Legal Analysis for Obviousness

35 U.S.C. §103(a) states (in pertinent part):

> "(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains..."

The Supreme Court in Graham v. John Deere, 338 U.S. 1, 148 U.S.P.Q. 459 (1966), stated that the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. Secondary considerations, such as commercial success, long felt

but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

The Supreme Court in KSR Int'l Co. v. Teleflex, Inc., 82 U.S.P.Q.2d 1385, 1395 (2007) further indicated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than produce predictable results. Accordingly, a court must determine whether the improvement is more than the predictable use of prior art elements according to their established functions. Id. at 1396. Since the claimed subject matter may involve more than a simple substitution of one known element for another or the mere application of a known technique to the prior art, it will often be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed. This analysis should be made explicit. Id. The Court further noted that a patent composed of several elements is not proved obvious merely by showing that each of its elements was, independently, known in the prior art. In these types of cases, identification of the reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the manner of the claimed invention can be important. Id. When the prior art teaches away from combining certain known elements, discovery of a successful manner to combine them is more likely be nonobvious. Id. at 1395.

(B.2) Claims 17 - 19, 21, 23, 51 - 53, 55 - 59, 61 and 62 are Patentable Over the Combination of the Augustine et al. Publication, and Mitsunaga et al. and Ikegame et al. Patents

Initially, independent claims 17, 51 and 57 each recite the features of:

(i) a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device;

(ii) fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) including an inlet portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet portions each including a connector for connection to portions of the intravenous fluid line; and

(iii) the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) including a plurality of nested (Claim 17) or concentric (Claims 51, 57) sections in fluid communication with the inlet and outlet portions and arranged adjacent each other to directly transfer heat between adjacent sections with the fluid flow in each section being opposite the fluid flow direction within each section adjacent that section, wherein the quantity of sections is based on providing a residence time for the fluid within the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F.

The Examiner takes the position that the Augustine et al. publication discloses the claimed

invention, except for the quantity of tubing section providing a residence time enabling warming of the fluid to a desired temperature with the range of 60 - 160° F. The Examiner further alleges that the Mitsunaga et al. patent teaches that it is known to vary the length of tubing to achieve warming to a desired temperature range, and that it would have been obvious to modify the device of the Augustine et al. publication with varied tubing length to provide for warming of liquid in the tubing to a desired temperature since such a modification would allow the device to provide sufficiently heated blood when treating patients.

The Examiner takes the further position that the combination of the Augustine et al. publication and Mitsunaga et al. patent disclose the claimed invention, except for the fluid line tubing including a spiral section wherein the fluid flow direction within each tubing section is opposite the fluid flow direction within each adjacent section. The Examiner further alleges that the Ikegame et al. patent teaches that it is known to use a spiral design with reversed fluid flow in adjacent tubing sections, and that it would have been obvious to modify the device of the Augustine et al. publication in view of the Mitsunaga et al. patent since such a modification would allow for even temperature distribution without the creation of thermal stress.

However, the Augustine et al. publication does not disclose, teach or suggest the above features recited in the independent claims. Rather, the Augustine et al. publication discloses an intravenous (IV) fluid warming system with a removable heat exchanger and a presence detector. The system is for warming an IV fluid before infusion into a body. The system includes a warming unit for warming the IV fluid and an inlet slot for receiving a heat exchanger, preferably embodied as a cassette . The heat exchanger is sized to fit into the inlet slot of the warming unit. The heat

exchanger has a heat exchanger membrane with a serpentine internal fluid pathway that is in fluid communication with a fluid inlet port and a fluid outlet port. The heat exchanger membrane consists of a first layer and a second layer joined together in a substantially continuous seam around their perimeters. The first and second layers may also be joined together at one or more locations within the seam to create the serpentine fluid pathway (e.g., See Abstract; and Paragraphs 0025 and 0030).

While the heat exchanger is in the warming unit, the IV fluid flows through the internal fluid pathway of the heat exchanger, warming the fluid. A heat exchanger presence detector is part of the warming system. The presence detector detects the presence of the heat exchanger when it is received in the warming unit. The presence detector enables the heating operation of the warming unit when the presence of the heat exchanger is sensed. A presence indicator to enable detection of the cassette by the presence detector is disposed on a rail of the cassette external of the fluid pathway (e.g., See Abstract; and Paragraphs 0030, 0032 and 0036).

Thus, the Augustine et al. publication discloses a warming unit with a heat exchanger having a serpentine fluid path and a presence detector to detect the presence of a cassette within the warming unit. There is no disclosure, teaching or suggestion of a fluid cassette including nested or concentric sections with opposing fluid flow directions, wherein the quantity of the nested or concentric sections is based on a fluid residence time to heat fluid to a desired temperature in a range of 60° F - 160° F as recited in the independent claims. In fact, the Augustine et al. publication discloses various manners of controlling the rate of warming of IV fluid, none of which concern a quantity of sections of the cassette providing a residence time for the warming device to heat the fluid to a desired temperature as recited in the claims. One manner is to sense fluid temperature and adjust warming

plates of the warming unit accordingly. Another manner is to control the flow rate of IV fluid through the defined path via a clamp or automated flow device (e.g., See Paragraph 0037). Moreover, the Examiner specifically concedes at Page 3 of the Office Action of October 18, 2007 that the Augustine et al. publication does not disclose these features.

The Mitsunaga patent does not compensate for the deficiencies of the Augustine et al. publication. Rather, the Mitsunaga et al. patent discloses a system for warming a fluid including a fluid warmer having a housing that retains therein a heating element, and a cartridge that is retained inside the housing and which receives heat from the heating element. The cartridge has a rigid plate having a first surface and a second opposing surface, with the plate having a meandering path provided therein. The cartridge also has a sheet of film that covers the first and second surfaces to form the fluid channel (e.g., See Abstract; Column 2, line 66 to Column 3, line 16; Column 5, lines 20 - 22; and Column 5, line 65 to Column 6, line 15). Thermistors are arranged to control the warming to enable the temperature of the fluid to vary at different regions of the cartridge (e.g., See Column 4, line 56 to Column 5, line 6).

Thus, the Mitsunaga et al. patent discloses a fluid warmer with a cartridge including a meandering fluid flow path. Accordingly, there is no disclosure, teaching or suggestion of a fluid cassette including nested or concentric sections with opposing fluid flow directions, wherein the quantity of the nested or concentric sections is based on a fluid residence time to heat fluid to a desired temperature in a range of 60° F - 160° F as recited in the independent claims. In fact, the Examiner specifically concedes at Page 3 of the Office Action of October 18, 2007 that the combination of the Augustine et al. publication and Mitsunaga et al. patent does not disclose these

features.

The Ikegame et al. patent does not compensate for the deficiencies of the Augustine et al. publication and Mitsunaga et al. patent. Rather, the Ikegame et al. patent discloses a heat sink for semiconductor elements including a pipe made of a heat conductive material, such as copper or aluminum. The pipe is bent at a middle portion thereof and wound such that forward and return passages for a liquid coolant are formed into a spiral (e.g., See Abstract and Column 3, lines 44 - 58). The number of turns of the spiral may be selected as desired according to the required diameter of the heat sink (e.g., See Column 3, lines 61 - 63; and Column 6, lines 17 - 20). The heat sink is utilized to contact electrodes of and cool semiconductor elements, such as diodes (e.g., See Column 4, lines 15 - 18).

Thus, the Ikegame et al. patent discloses a heat sink for semiconductor elements to cool those elements. There is no disclosure, teaching or suggestion of a fluid cassette including nested or concentric sections with opposing fluid flow directions, wherein the quantity of the nested or concentric sections is based on a fluid residence time to heat fluid to a desired temperature in a range of 60° F - 160° F as recited in the independent claims.

Since the proposed combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents does not disclose, teach or suggest each and every feature recited in independent claims 17, 51 and 57 as discussed above, the rejection is considered improper.

Claims 18 - 19, 21, 23, 52 - 53, 55 - 56, 58 - 59, 61 and 62 depend, either directly or indirectly, from independent claims 17, 51 or 57 and, therefore, include all the limitations of their parent claims. These claims are considered to overcome the combination of the Augustine et al.

publication, and Mitsunaga et al. and Ikegame et al. patents for substantially the same reasons discussed above in relation to their parent claims and for further limitations recited in the dependent claims.

In addition to the foregoing, there is no apparent reason to combine the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents to attain the claimed invention. The Augustine et al. publication is the primary document utilized by the Examiner within the rejection and discloses an intravenous (IV) fluid warming system with a removable heat exchanger and a presence detector as described above, while the Mitsunaga et al. patent discloses a system for warming fluid including a cartridge having a rigid plate with a meandering fluid path provided therein as described above. The Ikegame et al. patent discloses a heat sink for semiconductor elements as described above.

The Examiner proposes to modify the structure of the Augustine et al. cassette with varied tubing length based on an alleged teaching of a long passageway defined in the rigid plate of the Mitsunaga et al. cartridge. The Examiner further proposes to alter the structure of the modified Augustine et al. cassette with the configuration of the Ikegame et al. heat sink.

As discussed above, the Supreme Court indicated several factors for determining the existence of an apparent reason to combine known elements, including: interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art.

However, application of these factors to the subject case does not provide an apparent reason

to combine the cited documents. In particular, and with respect to the interrelated teachings of multiple documents, the Augustine et al. publication discloses that the rate of heating must be carefully matched to the to the rate of fluid flow, where a fluid warming system must calibrate the rate of fluid flow to the rate of heating (e.g., See Paragraph 0007). Calibration depends on many parameters that are inherent in the construction of the insertable heat exchanger, in the shape of the fluid flow path of the heat exchanger, and in the positioning of the heat exchanger in the warming unit. Misregistration between the fluid flow path of the heat exchanger and a corresponding shape of a heating element can result in undesirable temperatures (e.g., See Paragraph 0008). In a warming system where the design and construction of a removable heat exchanger are precisely optimally matched to the design, construction and performance of the warming unit, provisions to ensure proper orientation between the heat exchanger and warming unit would improve system efficiency, safety and cost (e.g., See Paragraph 0009). Accordingly, the Augustine et al. publication discloses an in-line IV fluid warming system that guarantees correct alignment between the heat exchanger and heating elements in the warming unit to satisfy these needs (e.g., See Paragraphs 0010 and 0012).

Thus, the Augustine et al. cassette and warming unit are specifically designed to be compatible with each other for proper operation and to achieve desired warming, where the presence detector ensures proper alignment for operation (e.g., See Paragraphs 0012 and 0013). Modification of the cassette and/or fluid flow path would cause improper operation (and heating) due to misalignment of the fluid path with heating elements and improper correlation of fluid flow and heating rates. In essence, the Examiner's proposal attempts to modify the Augustine et al. cassette to

a form that is inoperable with the warming unit. The apparent impracticality and technical incompatibility of the modified cassette with the warming unit provides an indication that the claimed invention is more than a predictable use of the combination of elements proposed by the Examiner.

The Examiner takes the position that modifying the cassette of the Augustine et al. publication in accordance with the Mitsunaga et al. patent would allow the modified Augustine et al. device to provide sufficiently heated blood when treating patients. However, the Augustine et al. publication discloses various manners of controlling the rate of warming of IV fluid as described above, none of which concern a quantity of sections of the cassette providing a residence time for the warming device to heat the fluid to a desired temperature as recited in the claims. Thus, no apparent reason or advantage exists for such a modification of the Augustine et al. cassette, especially since a fluid flow path change within the cassette would raise the impracticality and technical incompatibility issues discussed above.

With respect to the Ikegame et al. patent, this patent teaches away from combining the disclosed heat sink configuration with the modified Augustine et al. device to attain the claimed features. Specifically, the Ikegame et al. patent discloses that the number of turns of the spiral wound pipe are selected based on the desired diameter of the heat sink (e.g., See Column 3, lines 61 - 63; and Column 6, lines 17 - 20). Further, since the Ikegame et al. patent is directed toward cooling a semiconductor element, concern exists for the temperature of the semiconductor element, rather than the temperature of coolant flowing through the heat sink. Thus, in contrast to the claimed

invention, the heat sink is specifically configured to include a number of turns sufficient to enable the heat sink to achieve the desired size or surface area for the semiconductor element.

The Examiner takes the position that altering the structure of the modified Augustine et al. device to include the configuration of the Ikegame et al. heat sink would allow for even temperature distribution without the creation of thermal stress. However, the Examiner's reasons for altering the modified Augustine et al. device with the configuration of the Ikegame et al. heat sink are misplaced. In particular, the Ikegame et al. patent discloses that prior heat sink configurations provided temperature differences of the coolant at the fluid passage inlet and outlet, thereby creating thermal stress in the semiconductor element being cooled (e.g., See Column 3, lines 26 - 32). The Ikegame et al. patent further indicates that the disclosed heat sink configuration enables the temperature of the heat sink to be distributed evenly, and that thermal stress in the semiconductor element can be substantially eliminated (e.g., See Column 4, lines 20 - 23).

Thus, the Ikegame et al. patent discloses reduction of thermal stress in the semiconductor element being cooled. Since the Augustine et al. cassette is not utilized as a heat sink to cool an external semiconductor element, but rather, to heat fluid flowing therein within a warming device as described above, the reduction of thermal stress on an external element appears to provide no basis for the combination proposed by the Examiner.

In addition, the Mitsunaga et al. patent discloses that the cartridge provides regions with different fluid temperatures (e.g., See Column 4, line 56 to Column 5, line 6) as discussed above. Accordingly, the reason provided by the Examiner for the proposed combination (as well as the

teachings of the Ikegame et al. patent) of achieving an even temperature distribution is in direct contrast to the teachings of the Mitsunaga et al. patent.

With respect to the remaining factors for determining an apparent reason to combine elements, a person having ordinary skill in the art would generally recognize the impracticality and technical incompatibility of adjusting the fluid flow path of the Augustine et al. cassette as discussed above. Thus, effects of demands known to the design community or present in the marketplace are unlikely to provide an apparent reason to modify the Augustine et al. cassette or, for that matter, alter the Augustine et al. cassette in accordance with Mitsunaga et al. cartridge and Ikegame et al. semiconductor element heat sink. In fact, the devices within the documents cited by the Examiner (Augustine et al. publication and Mitsunaga et al. patent) pertaining to cassettes or cartridges for intravenous or transfusion fluid warming employ serpentine or meandering fluid flow paths, thereby suggesting that the demands of the design community or present in the marketplace are directed toward these types of paths, and not the configuration of the Ikegame et al. semiconductor heat sink. Accordingly, the proposed combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents does not render the claimed invention obvious.

(B.3) Claims 20, 54 and 60 are Patentable Over the Combination of the Augustine et al. Publication and Mitsunaga et al. and Ikegame et al. Patents

As discussed above, the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. It will often be necessary for a court to look

to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine known elements in the fashion claimed.

Claims 20, 54 and 60 depend, either directly or indirectly, from independent claims 17, 51 and 57, respectively, and therefore include all the limitations of their parent claims. These claims are considered to overcome the combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents for substantially the same reasons discussed above in relation to their parent claims, and for further limitations recited in these claims as discussed below.

Specifically, claims 20, 54 and 60 further recite the feature of a conductive contact disposed about a portion of the fluid line tubing (Claim 20)/fluid flow means (Claim 54)/fluid conduit (Claim 60) and detectable by the intravenous fluid warming device to indicate the presence of the cassette within the warming device and control device operation.

The Examiner takes the position that the combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents discloses the claimed invention, and further alleges that the Augustine et al. publication discloses a conduction contact disposed about a portion of the fluid flow means to indicate the presence of a cassette within the warming device.

However, the Augustine et al. publication discloses a cassette presence circuit to detect the presence of the cassette in the warming unit. The cassette presence circuit includes components disposed on the cassette, and in or on the housing of the warming unit (e.g., See Paragraph 0032).

Although the cassette includes a presence indicator 153 (e.g., made from a soft ferro-magnetic material) for the cassette presence circuit, the presence indicator is disposed on a rail of the cassette external of the fluid flow passage (e.g., See Figs. 1 and 8; Paragraph 0030), as opposed to being disposed about a portion of the fluid conduit as recited in the claims.

Since the proposed combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents does not disclose, teach or suggest each and every feature recited in claims 20, 54 and 60 as discussed above, this rejection is considered improper.

In addition to the foregoing, there is no apparent reason to combine the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents as discussed above.

(B.4) Claim 22 is Patentable Over the Combination of the Augustine et al. Publication, and Mitsunaga et al. and Ikegame et al. Patents

As discussed above, the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. It will often be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine known elements in the fashion claimed.

Claim 22 depends directly from claim 21 and indirectly from independent claim 17.

Accordingly, claim 22 includes all the limitations of its parent claims and is considered to overcome the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents for substantially the same reasons discussed above in relation to its parent claims and for further limitations recited in the claim. In particular, claim 22 further recites the fitting including a thermally conductive member disposed within the fitting and in direct contact with fluid flowing through the fitting, wherein the thermally conductive member receives the temperature sensor to measure temperature of the fluid flowing within the fluid cassette.

Initially, the Examiner has not provided a sufficient showing to support an obviousness rejection. In particular, the Examiner does not mention in the rejection the specific features of this dependent claim (e.g., a fitting including a thermally conductive member disposed within the fitting and in direct contact with fluid flowing through the fitting, wherein the thermally conductive member receives the temperature sensor) or, for that matter, the relevant sections of the cited documents pertaining to those features and the manner and reasons for combining the cited documents to render the claimed features obvious.

Although the Examiner indicates in the rejection that the Augustine et al. publication discloses a temperature sensor, this temperature sensor is merely described as being disposed within an outlet port 148 of the heat exchanger (e.g., See Paragraph 0030). There is no disclosure, teaching or suggestion of a thermally conductive member disposed within a fitting in direct contact with fluid flowing in the fitting, and receiving the temperature sensor to measure temperature of the fluid as recited in the claim.

Since the proposed combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents does not disclose, teach or suggest each and every feature recited in claim 22 as discussed above, this rejection is considered improper.

In addition to the foregoing, there is no apparent reason to combine the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents as discussed above.

(8) Claims Appendix

17. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device, said cassette comprising:

fluid line tubing including an inlet tubing portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet tubing portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet terminals each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid line tubing further includes a spiral portion including a plurality of nested tubing sections in fluid communication with said inlet and outlet tubing portions and arranged adjacent each other to directly transfer heat between said adjacent tubing sections to heat said fluid from said intravenous fluid line, each said tubing section defining a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each tubing section is opposite the fluid flow direction within each tubing section adjacent that section;

wherein the quantity of said tubing sections within said spiral portion is based on providing a residence time for said fluid within said fluid line tubing enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

18. The fluid cassette of claim 17, wherein said tubing sections are concentric and define

a fluid cassette annular section, and said inlet and said outlet tubing portions extend tangentially from said annular section.

19. The fluid cassette of claim 18, wherein said annular section includes an intermediate section to direct fluid flow received from said inlet terminal in a reverse direction through said annular section tubing sections toward said outlet terminal.

20. The fluid cassette of claim 17 further including a conductive contact disposed about a portion of said fluid line tubing and detectable by said intravenous fluid warming device to indicate the presence of said cassette within that warming device and control device operation.

21. The fluid cassette of claim 17 further including a fitting in fluid communication with said fluid line tubing to permit fluid to flow within said fitting, wherein said fitting receives a temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

22. The fluid cassette of claim 21, wherein said fitting includes a thermally conductive member disposed within said fitting and in direct contact with fluid flowing through said fitting, wherein said thermally conductive member receives said temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

23. The fluid cassette of claim 17 further including at least one engagement member to facilitate manipulation, insertion and removal of said fluid cassette within said warming device.

51. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device, said cassette comprising:

fluid flow means including an inlet portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet portions each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid flow means further includes a plurality of concentric sections in fluid communication with said inlet and outlet portions and arranged adjacent each other to directly transfer heat between said adjacent sections to heat said fluid from said intravenous fluid line, each said concentric section defines a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section;

wherein the quantity of said sections is based on providing a residence time for said fluid within said fluid flow means enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

52. The fluid cassette of claim 51, wherein said concentric sections define a fluid cassette annular section, and said inlet and said outlet portions extend tangentially from said annular section.

53. The fluid cassette of claim 52, wherein said annular section includes an intermediate section to direct fluid flow received from said inlet terminal in a reverse direction through said annular section toward said outlet terminal.

54. The fluid cassette of claim 51 further including a conductive contact disposed about a portion of said fluid flow means and detectable by said intravenous fluid warming device to indicate the presence of said cassette within that warming device and control device operation.

55. The fluid cassette of claim 51 further including a fitting in fluid communication with said fluid flow means to permit fluid to flow within said fitting, wherein said fitting receives a temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

56. The fluid cassette of claim 51 further including at least one engagement means for facilitating manipulation, insertion and removal of said fluid cassette within said warming device.

57. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid

warming device, said cassette comprising:

a fluid conduit including an inlet portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet portions each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid conduit further includes a plurality of concentric sections in fluid communication with said inlet and outlet portions and arranged adjacent each other to directly transfer heat between said adjacent sections to heat said fluid from said intravenous fluid line, each said concentric section defines a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section;

wherein the quantity of said sections is based on providing a residence time for said fluid within said fluid conduit enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

58. The fluid cassette of claim 57, wherein said concentric sections define a fluid cassette annular section, and said inlet and said outlet portions extend tangentially from said annular section.

59. The fluid cassette of claim 58, wherein said annular section includes an intermediate section to direct fluid flow received from said inlet terminal in a reverse direction through said

annular section toward said outlet terminal.

60. The fluid cassette of claim 57 further including a conductive contact disposed about a portion of said fluid conduit and detectable by said intravenous fluid warming device to indicate the presence of said cassette within that warming device and control device operation.

61. The fluid cassette of claim 57 further including a fitting in fluid communication with said fluid conduit to permit fluid to flow within said fitting, wherein said fitting receives a temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

62. The fluid cassette of claim 57 further including at least one engagement member to facilitate manipulation, insertion and removal of said fluid cassette within said warming device.

(9) Evidence Appendix

None.

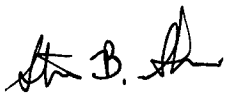
(10) Related Proceedings Appendix

None.

(11) Conclusion

In view of the foregoing, it is submitted that the rejections of claims 17 - 23 and 51 - 62 are improper and, accordingly, the Board is respectfully requested to reverse the rejections and order that this application be allowed.

Respectfully submitted,



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